

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Christopher J. Dinsmore, et al.	Confirmation No.:	3814
Serial No.:	10/523,285	Art Unit:	1626
Filed:	February 3, 2005	Examiner:	Shailendra Kumar
For:	TYROSINE KINASE INHIBITORS	Attorney Docket No:	21202YP

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

MAIL STOP PATENT EXT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The above-identified application issued on July 14, 2009. The total patent term adjustment calculated by the Patent Office for this application is 352 days. Applicants hereby respectfully request reconsideration of the patent term adjustment for this application. Specifically, Applicants believe that the total patent term adjustment should be **616** days.

In support of this request, Applicants submit the following statement of facts pursuant to 37 C.F.R. § 1.705(b).

- (i) Applicants agree with the Patent Office that the patent term adjustment due to examination delay under 37 C.F.R. § 1.702(a) is 538 days. 511 days under 37 C.F.R. § 1.703 (a) (1) and 27 days under 37 C.F.R. § 1.703(a)(6). However, the Patent Office has failed to consider the patent term adjustment calculated under 37 C.F.R. § 1.702(b) due to the failure of the Office to issue a patent within three years after the date on which the application was filed. According to 37 C.F.R. § 1.702(b)(1), the period of adjustment under 37 C.F.R. § 1.702(b), does not include the number of days in the period beginning on the date on which a request for continued examination of the application was filed and ending on the date the patent was issued. This application was filed on February 3, 2005. Accordingly, the application should have issued three years later, on February 3, 2008. A request for examination was filed on September

12, 2008. According to 37 C.F.R. § 1.702(b)(1), the delay is **222** days (from 02/03/2008 to 09/12/2008).

- (ii) In addition, applicants note that the Patent Office has attributed 41 days of applicant delay from the day an Office communication was mailed (May 6, 2009) to the day applicants filed a response (June 4, 2009). According to 37 C.F.R. § 1.704 (b), an applicant shall have been deemed to have failed to engage in reasonable efforts to conclude processing of an application for the cumulative total periods of time in excess of three months that are taken to reply to any notice by the office. Here, applicants responded to an Office communication within 29 days, which is less than three months. Applicants engaged in reasonable efforts to conclude processing of the application, therefore, the 29 day period should not be counted as applicant delay.
- (iii) Further, applicants note that the Patent Office has made a mathematical error in the calculation of applicants' delay under 37 C.F.R. § 1.704 (c)(10). Applicants filed a communication on February 17, 2009 to update the inventor's address. On May 6, 2009, the Examiner mailed an Office communication in response to the communication. The duration between 02/17/2009 to 05/06/2009 is **78** days, not 79 days. Accordingly, the periods for reduction due to applicants' delay under 1.704 is $63+3+78=$ **144** days.
- (iv) Under *Wyeth v. Dudas*, the adjustment sought under 37 C.F.R. § 1.703(f) is the sum of the periods under § 1.702(a)(**538** days) and § 1.702(b)(**222** days), less the additional delays attributable to Applicant (**144** days). Accordingly, Applicant respectfully requests an adjustment of patent term under § 1.703(f) to indicate a total PTA of **616** days.

In support of Applicant's request for the adjustment under § 1.703(f) to include the sum of the periods under § 1.702(a) and § 1.702(b), rather than the greater of these two periods, Applicants rely on the decision of the U.S. District Court for the District of Columbia in *Wyeth v. Dudas*, Civil Action No. 07-1492 (D.D.C. September 20, 2008). In that decision, the Court construed the meaning of the statutory provision regarding the limitations on extensions granted for delays under 35 U.S.C. § 154(b)(1)(A-C):

(A) In general. -- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). The court stated that “[t]he operative question under 35 U.S.C. § 154(b)(2)(A) is whether periods of delay attributable to grounds specified in paragraph (1) overlap.” *See* Memorandum Opinion at p. 8. (internal quotations omitted). In the opinion of the district court, “[t]he only way that periods of time can “overlap” is if they occur on the same day.” *Id.* The court thus rejected the Patent Office’s view that any administrative delay under 35 U.S.C. § 154(b)(1)(A) (“A delays”) overlaps with any 3-year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B) (“B delay”). In the district court’s view, the only A delays which overlap with the B delay are those which occur *after* the B period begins, which is when the Patent Office has failed to issue a patent within three years of an application’s filing date, and not before. *See* Memorandum Opinion at p. 5-6, 9.

Applying the rule in *Dudas* to the present facts, the period for A delay is 538 days, of which 511 days occurred before February 3, 2008 (three years from the filing date of this application); and of which 27 days occurred after February 3, 2008. The period for B delay begins on February 4, 2008 and ends on filing a request for examination, September 12, 2008, a period of 222 days. Since the 511 day A delay occurred before the B period began, and 27 day A delay occurred after the B period ended, there is no overlap between the A delay and the B delay. Accordingly, the total patent term adjustment should be calculated from the sum of the non-overlapping A and B periods (538+222) days, less the delays due to applicant, 144 days, giving a total of 616 days.

Applicants note that *Wyeth* is currently on appeal at the Federal Circuit. Therefore, Applicants respectfully request that the USPTO hold its decision regarding the three-year provision in abeyance until the Federal Circuit has rendered its decision.

Applicant notes that the above-identified application is not subject to a terminal disclaimer.

In summary, Applicant respectfully requests an adjustment of patent term under 37 C.F.R. § 1.703(f) to indicate a total PTA of 616 days. Pursuant to 37 C.F.R. § 1.705(d) and § 1.18(e), the fee required for filing this application for patent term adjustment is believed to be **\$200.00**. Please charge the required fee to Deposit Account No. 13-2755, Customer No, 00210, Reference No.: 21202YP.

Date: September 14, 2009

/Li Su, Reg. No. 45141/

By: Li Su

Attorney for Applicant(s)

Reg. No. 45,141

MERCK & CO., INC.

P.O. Box 2000

Rahway, NJ 07065-0907

(732) 594-5455